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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------------------|------------------|
| 10/663,577 | 09/16/2003 | Robert G. Dennis | UOM 0294 PUS | 4495 |
| 22045 | 7590 | 10/24/2006 | | |
| BROOKS KUSHMAN P.C. 1000 TOWN CENTER TWENTY-SECOND FLOOR SOUTHFIELD, MI 48075 | | | EXAMINER GOUGH, TIFFANY MAUREEN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1657 | |

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/663,577

Applicant(s)

DENNIS ET AL.

Examiner

Tiffany M. Gough

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-8,10-21 and 23-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-21 and 23-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed 7/5/2006 has been received and entered into the case.

Claims 1,3-8,10-21,23-40 are pending and have been considered on the merits. All arguments and amendments have been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 (and all dependent claims) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification, as originally filed, in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the amendment "...without disposing the cells within an exogenous scaffold material..." introduces new matter, which is not described in the specification. Applicant has only stated that the cardiac muscle construct self-organizes without the need for an exogenous scaffold (see p.3 of specification). Therefore, "without disposing the cells WITHIN an exogenous scaffold material ", changes the scope of the claims and applicants invention for which no support is provided. This is a new matter rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 (and all its dependent claims) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 has been amended to read "...and subsequently permit the monolayer to detach..." This statement is indefinite for the following reason: it does not seem that the monolayer necessarily DOES detach to self-organize into a three dimensional construct. The monolayer is "permitted" to detach but does not state that it absolutely does.

Claim 21 recites the limitation "the system according to claim 17...." There is insufficient antecedent basis for this limitation in the claim because claim 17 is drawn to a method not a system.

The following 112 2nd rejection is maintained.

The function of the "anchors" in claims 9 and 10 is unclear. It appears that the anchors may actually be serving as a scaffold-like structure, enabling the cells to grow around the anchors allowing cell layers to form and enabling ingrowth of tissue. One skilled in the art may be led to consider the claimed "anchors" as a "scaffold" in regards to the vagueness of the word scaffold used in applicants invention. Furthermore, the spatial relationship of the anchors appears to be essential for the growth of cells in the

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invention and should be clearly defined. Therefore, claims 9-11,22-24 are rejected under 35 U.S.C 112, second paragraph.

Applicants arguments and amendments to the claims are not persuasive and do not clarify the relationship of the anchors in conjunction with "an exogenous scaffold." It still appears as if the anchors are serving as an exogenous scaffold material allowing cells to attach and grow on and in the anchors (see specification p.8, lines 13-18). Thus, applicants arguments of the differences between the claimed anchors and scaffolds is not persuasive.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,3-7,10-21,23-27,29,32-36 and 40 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-

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3,5-9,12,13,15-19,21-23,26,28-31 of U.S. Patent No. 6,207,451 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because 6,207,451 B1 teaches that the mammalian muscle construct comprising myogenic precursor cells may include cardiac muscle cells, thus, the constructs and methods appear to be drawn to the same subject matter.

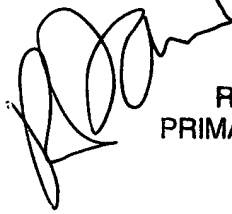
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tiffany M. Gough whose telephone number is 571-272-0697. The examiner can normally be reached on M-F 8-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tiffany Gough

A handwritten signature in black ink, appearing to read 'Ruth Davis', with a long, sweeping horizontal line extending to the right.

RUTH DAVIS
PRIMARY EXAMINER